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10/519,881	12/30/2004	Tetsuya Sakata	10921.0268USWO	7393

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EXAMINER	
DOUGHERTY, SEAN PATRICK	
ART UNIT	PAPER NUMBER
3736	
MAIL DATE	DELIVERY MODE
03/28/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/519,881	SAKATA ET AL.	
	Examiner	Art Unit	
	SEAN P. DOUGHERTY	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/30/2004, 02/19/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This is the *initial* Office action based on the 10/519881 application filed December 30, 2004. Claims 1-15, as originally filed, are currently pending and have been considered below.

Claim Objections

Claim 5 objected to because of the following informalities:

Claim 5 recites the limitation "the analyzer" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-13 & 15 are rejected under 35 U.S.C. 102(a) as being anticipated by Farhi (US Patent No. 7,001,364).

1. Farhi discloses a method of setting a lancing member to a lancing device, the method comprising:

a first step for causing a lancing member (device best seen in Fig. 7C and Fig. 7D) formed integral with a cap (distal most end of second shield [14]) covering a needle (needle [12]) to be held by a holder (proximal most end of second shield [14] including knobs [16]) of a lancing device; and

a second step for breaking a boundary between the cap and the lancing member by rotating the lancing member relative to the cap utilizing a rotating means prearranged at the lancing device, the second step performed during or after the first step (arrow showing direction of twist to unlock, 28; "before the injection, the second shield 14 is twisted, which unlocks the mechanism" col. 6, lines 20-22; best seen in Fig. 7B).

2. Farhi discloses the method according to claim 1, further comprising:

a third step for exposing the needle by detaching the cap from the lancing member after the second step ("allowing the second shield 14 to retract into first shield 18 during the injection" col. 6, lines 22-23; best seen in Fig. 7C).

3. Farhi discloses the method according to claim 1, wherein:

the lancing device comprises a housing (first shield [18]) including a tip end formed with an opening (end of first shield [18] through which second shield [14] is received), the holder being reciprocally movable in the housing (col. 7, lines 3-6), and

wherein the rotating means comprises a cam mechanism for rotating the holder and (knobs [16] including guided grooves [24]) the lancing member utilizing a pressing force exerted when the holder is pressed into the housing by the lancing member (col. 6, lines 20-24; col. 7, lines 3-6).

4. Farhi discloses the method according to claim 3, where:

the lancing member is held by a supporting member (needle hub [11]) including a sheath (area formed by first shield [18] generally around where needle hub [11] is located), and wherein in the first step, the sheath is slidably fitted to an end of the housing, the lancing member being pressed against the holder to be pushed into the housing (col. 6, lines 20-24; col. 7, lines 3-6).

5. Farhi discloses the method of claim 4, wherein:

the supporting member (needle hub [11]) holds an analyzer (col. 3, lines 17-18); and

wherein in the first step, the analyzer is attached to the lancing device when the lancing member is held by the holder (col. 7, lines 22-27).

6. Farhi discloses the method according to claim 1, wherein:

the rotating means comprises a motor (spring [13]), and wherein in the second step, the lancing member is rotated by driving force of the motor (col. 6, lines 50-52).

7. Farhi discloses a lancing device comprising:

a holder (proximal most end of second shield [14] including knobs [16]) for holding a lancing member (distal most end of second shield [14]);

a moving mechanism for advancing the holder in a predetermined direction (knobs [16]); and

rotating means for rotating the lancing member when the lancing member is about to be held by the holder or after the lancing member is held by the holder (guiding grooves [24]).

8. Farhi discloses the lancing device according to claim 7, wherein:

the holder holds the lancing member in a manner such that the holder and the lancing member are not rotatable relative to each other, wherein the rotating means rotates the holder together with the lancing member (col. 6, lines 20-24; col. 7, lines 3-6).

9. Farhi discloses the lancing device according to claim 8, wherein:

the rotating means comprises a cam mechanism for rotating the holder when the holder retracts in a direction opposite to the predetermined direction (guiding grooves [24]).

10. Farhi discloses the lancing device according to claim 9, further comprising:

a cylindrical housing that contains the holder therein and includes a tip end formed with an opening (end of first shield [18] through which second shield [14] is received),

wherein the cam mechanism includes a first groove which is provided at one of the housing and the holder and is inclined relative to a longitudinal axis of the housing (cam mechanism (guide grooves [24]) provided inclined relative to a longitudinal axis of a housing is circled below in Fig. 7A), and also includes a protrusion which is provided at the other one of the housing and the holder and is fitted in the first groove (knob [16]).

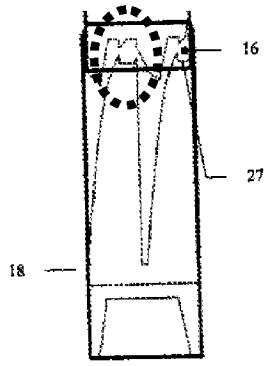

FIG.7A

11. Farhi discloses the lancing device according to claim 10, wherein:

the cam mechanism further includes a second groove connected to the first groove and extending in parallel to the axis of the housing, and wherein the protrusion passes through the second groove when the holder advances (cam mechanism (guide grooves [24]) connected to the first groove and extending in parallel to the axis of the housing is circled below in Fig. 7A).

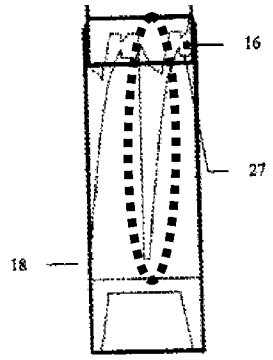

FIG.7A

12. Farhi discloses the lancing device according to claim 8, wherein:

the rotating means comprises a motor (spring [13]) and a member for transmitting rotating force of the motor to the holder (col. 6, lines 50-52).

13. Farhi discloses the lancing device according to claim 7, further comprising:

a holding portion for removably holding an analyzer used for analyzing a sample taken by piercing. Examiner notes that needle hub [11] is fully capable as acting as a holding portion for removably holding an analyzer used for analyzing a sample taking by piercing.

15. Farhi discloses a cam mechanism comprising:

a cylindrical housing (first shield [18]);

a movable member contained in the housing for moving reciprocally in first and second directions parallel to a longitudinal axis of the housing (second shield [14]);

a first groove inclined relative to the axis of the housing (cam mechanism (guide grooves [24]) provided inclined relative to a longitudinal axis of a housing is circled above in Fig. 7A, picture associated with claim 10 rejection) and a second groove connected to the first groove and extending linearly in parallel to the axis of the housing (cam mechanism (guide grooves [24]) connected to the first groove and extending in parallel to the axis of the housing is circled above in Fig. 7A, picture associated with claim 11 rejection), the first and the second grooves being provided at one of the housing and the movable member (grooves provided in housing; see Fig. 7A through 7D); and

a protrusion provided at the other one of the housing and the movable member, the protrusion extending into the first groove and the second groove (knobs [16]);

wherein the protrusion moves in the first groove when the movable member moves in the first direction, and moves in the second groove when the movable member moves in the second direction (see Figs 7A through 7D).

Claims 1 & 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Japanese Utility Model Application No. 84501/1992 (cited in IDS).

1. Japanese Utility Model Application No. 84501/1992 discloses a method of setting a lancing member to a lancing device, the method comprising:

a first step for causing a lancing member (lancing member, 15) formed integral with a cap (cap, 15) covering a needle (needle, 14) to be held by a holder of a lancing device (holder, 9); and

a second step for breaking a boundary between the cap and the lancing member by rotating the lancing member relative to the cap utilizing a rotating means prearranged at the lancing device, the second step performed during or after the first step (Fig. 2 establishes threads 11 which indicate rotation to attach to holder 9 facilitating in the breaking a boundary between a cap and a lancing member best seen in Fig. 3).

7. Japanese Utility Model Application No. 84501/1992 discloses a lancing device comprising:

a holder for holding a lancing member (holder, 9);

a moving mechanism for advancing the holder in a predetermined direction (indicated by arrow in Fig. 2); and

rotating means for rotating the lancing member when the lancing member is about to be held by the holder or after the lancing member is held by the holder (threads, 11).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Farhi (cited above) in view of Fosslien (US Patent No. 4,311,484).

14. Farhi does not appear to explicitly discloses the lancing device according to claim 13, further comprising:

a control circuit for analyzing the sample using the analyzer.

However, Fosslein discloses a reference in analogous art including a control circuit for analyzing the sample using the analyzer ("delivering the sample to an analyzer" abstract, lines 1-4; sensor control circuitry best seen in Fig. 26A-26E).

At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Farhi and Fosslien before him or her to further include the control circuit for the analysis of a sample using the analyzer of Fosslien with the needle injection device of Farhi.

The motivation for doing so would have been "to provide a needle safety cap device which is compatible with all needle injection devices" (Farhi: col. 3, lines 18-19) without "modifying the syringe system" (Farhi: col. 7, line 25) the needle injection device including a hollow needle to draw in a specimen (Fosslien: abstract, line 8) which connects the needle to the sample analyzer (Fosslien: abstract, lines 9-10) for analysis (Fosslien: col. 2, lines 15-16), the analyzer including control circuitry (best seen in Fig. 26A-26E).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Kovelman (US Patent No. 5,964,731).

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SEAN P. DOUGHERTY whose telephone number is (571)270-5044. The examiner can normally be reached on Monday-Thursday, 7:00am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. P. D./
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736